# LOCKING HANDLE DEPLOYMENT MECHANISM FOR MEDICAL DEVICE AND METHOD

## REFERENCE TO RELATED APPLICATION

This patent application is a divisional patent application, of United States Patent Application Serial Number 10/175,113 filed on June 18, 2002, which is a continuation-in-part of United States Patent Application Serial Number 09/975,873 filed on October 12, 2001.

## BACKGROUND AND SUMMARY OF THE INVENTION

1. Technical Background:

The present invention relates generally to medical devices, and more particularly to a medical device delivery system with an improved locking handle having a compound mechanism.

2. Discussion:

The present invention involves medical devices, and also the delivery systems used to convey them to a desired location for treatment, and then deploy them in position. Many such medical devices are resiliently compressed to a smaller initial size for containment, protection, storage and eventual delivery from inside a catheter system. Upon deployment, the medical devices may resiliently expand to a larger deployed size.

A successful example of a delivery catheter system, in this case for a self-expanding stent, is described in United States Patent number 6,019,778 entitled "Delivery Apparatus For A Self-Expanding Stent," to Wilson et al. issued February 1, 2000. The disclosure of this patent is incorporated by reference in the present application, and generally discloses a flexible catheter system shown in a representative diagrammatic form in Figure 10, including coaxially arranged inner and outer catheter members, each having a hub affixed to its proximal end. The outer sheath is described in the '778 patent as an elongated tubular member having distal and proximal ends, which is made from an outer polymeric layer, an inner polymeric layer, and a braided reinforcing layer between them. The inner shaft is described in the '778 patent as being located coaxially within the outer sheath and has a flexible tapering distal end, which generally extends distally beyond the distal end of the outer sheath. The inner shaft member also is shown as including a stop which is positioned proximal from the distal end of the outer sheath. A self-expanding stent is located within the outer sheath, and is located between the stop on the inner shaft member and the outer sheath distal end. To deploy the stent the outer sheath is withdrawn by a physician in a proximal direction, while the inner shaft member is held in position.

Additional examples of different types of known self-expanding stent delivery systems are shown in United States Patent number 4,580,568 issued to Gianturco on April 8, 1986; as well as United States Patent number 4,732,152 issued to Wallsten et al. March 22, 1988.

In operation, these known medical device delivery systems are generally advanced within a body of a patient along a desired vascular path or other body

passageway, until the medical device within the catheter system is located at a desired site for treatment. While watching the relative positions of the medical device and the catheter system components with respect to a stenosis on a video x-ray fluoroscopy screen, the physician holds the proximal hub attached to the inner shaft member in a fixed position with one hand, while simultaneously gently withdrawing the proximal hub attached to the outer tubular sheath with the other hand.

For several reasons, this deployment operation may require some measure of delicate skill. For example, among these reasons is the dynamic blood flow at the desired site for treatment, which may be further disrupted by the presence of a lesion or stenosis to be treated. Another factor is the gradual resilient expansion of a medical device as the outer sheath is retracted. This gradual expansion presents an opportunity for a possible reverse "watermelon-seed" phenomenon to occur. This reverse watermelon-seed effect may cause the resilient medical device to tend to push the outer sheath back in a proximal direction with a force that tends to change as the sheath is progressively retracted.

As a result, the physician may need to accurately hold the two proximal hubs in a specific relative position, holding them against this expansion force, while attempting to very accurately position the medical device up until contact with the anatomy. One of the possibilities that may affect the positioning of the deployed medical device is that the inner shaft should preferably be held stationary in the desired position. If the physician's hand that holds the inner shaft hub does inadvertently move during deployment, it is possible that the medical device may be deployed in a non-optimum position.

Another possible factor is that the inner and outer catheter shaft members, like any other elongated object, do not have infinite column strength, which may present an

opportunity for the position and movement of each proximal hub to differ from the position and movement of the respective distal ends of the inner and outer shaft members. Yet another factor is that the position of the medical device may be adjusted up until the point at which a portion of the expanding portion of the medical device touches the sidewalls of the body passage, so that the position of the medical device should preferably be carefully adjusted until immediately before a portion of the medical device touches the anatomy.

Some known catheter systems require two-handed operation, such as those with a pair of independent hubs, one hub on the inner and outer shaft member, respectively. Other known catheter systems include a pistol and trigger grip, with a single mode of deployment, involving a single trigger pull to deploy the associated medical device.

Accordingly, although physicians may be capable of operating such known systems with great skill, it is desirable to provide an improved catheter delivery system capable of facilitating easier and more accurate deployment and positioning of resiliently expansive medical device.

In addition, it is desirable to provide an advanced catheter deployment mechanism having two modes of operation. In the first mode of operation, the delivery mechanism preferably provides a precisely adjustable link between the inner and outer catheter shaft members, such that the relative position of the outer sheath with respect to the inner catheter shaft member can be precisely and selectively adjusted. Yet at any selected position, the delivery mechanism should preferably maintain this selected relative position of the inner and outer catheter shaft members, while resisting any force that may be present tending to move the inner or the outer catheter shaft members with respect to

the other. In a second mode of operation, the delivery mechanism should preferably enable the physician to rapidly withdraw the outer tubular sheath with respect to the inner catheter shaft member preferably in a proximal direction with a single easy motion.

Moreover, it is desirable to provide an integrated and ergonomic handle for easily and effectively operating the stent delivery system of the present invention.

It is also desirable to provide a handle for operating a stent delivery system that includes a locking mechanism. Such a locking mechanism preferably resists inadvertent or accidental movement or retraction of the stent delivery system components during packaging, sterilization, shipping, storage, handling and preparation. The lock preferably is spring-loaded, or otherwise easily released.

In addition, the handle mechanism may also provide for activation and retraction of the sheath only, while resisting an attempt to re-advance the sheath and re-cover the medical device.

Another embodiment of the present invention involves providing a single actuator for both or all of the multiple modes of operating the handle and delivery system.

Additional embodiments of the present invention relate to different types of movement to actuate each mode of operation. For example, a single actuator may rotate for a first mode of operation, and slide in another mode. Or a single actuator may rotate in one direction for a first mechanical advantage, and rotate in another direction for a different mechanical advantage.

The present invention accordingly provides such a desirable medical device delivery mechanism, with an integrated and ergonomic handle replacing the functions of

the separate proximal hubs of the prior inner and outer catheter shaft members, providing desired dual modes of operation as well as the desired locking system.

These and other various objects, and advantages and features of the invention will become apparent from the following description and claims, when considered in conjunction with the appended drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an external perspective view of a medical device delivery system handle, arranged according to the principles of the present invention;

Figure 2 is a partial longitudinal cross-sectional view of a medical device delivery system arranged according to the present invention in an initial configuration;

Figure 3 is a partial side elevation view of the medical device delivery system of Figure 2;

Figure 4 is a partial top plan cross-sectional view of the medical device delivery system of Figure 2;

Figure 5 is a partial longitudinal cross-sectional view of certain components of a medical device delivery system according to the present invention;

Figure 6 is a perspective view of certain components of a medical device delivery system according to the present invention;

Figures 7-10 are partial longitudinal cross-sectional views of certain components of a medical device delivery system according to the present invention; and

Figures 11-14 are perspective views of proximal and distal ends of a medical device delivery system arranged according to the principles of the present invention, in various operating configurations.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description of the preferred embodiments of the present invention is merely illustrative in nature, and as such it does not limit in any way the present invention, its application, or uses. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

Referring to the drawings, a medical device delivery system is depicted, with one of the preferred embodiments of the present invention being shown at 10. The illustrated stent delivery catheter system 10 of course depicts only one of many different medical device delivery systems designs that are within the scope of the present invention. The present invention may be designed to deliver and deploy any suitable medical device. However, for clarity and convenience, the present detailed description will only describe such an example of a delivery system for stents.

Among the possible medical device delivery systems that may be used with the present invention is any appropriate system in which an outer sheath is provided, surrounding an inner shaft. A medical device may be carried within the outer sheath during delivery to a desired site for treatment, where the outer sheath may be retracted, while the inner shaft and medical device are held in place.

The novel concept of the present invention may also be used for medical device delivery systems in which the motion of the operator to deploy the medical device is selected from any suitable possibility, including axial motion in the proximal direction or distal direction, or a rotational motion, a trigger actuator, a gear mechanism, or any other type of actuator that may be preferred, depending upon a particular application. Indeed, the present unique concept may be used for medical device delivery systems in which the

medical device is deployed in any suitable manner, including retracting an outer sheath in a proximal or distal direction, or uncovering a medical device in various ways, including withdrawing portions of outer sheath members in proximal and distal directions, simultaneously or sequentially.

The present invention may preferably have several advantages individually, or any combination of such advantages, including for example: (i) single-handed operation of the medical device delivery system; (ii) a mechanism providing leverage or mechanical advantage, to adjust or reduce the forces needed to operate the system; (iii) improved accuracy in positioning the medical device during deployment; and (iv) multiple operational modes of operation, including for example a first mode of fine and precise control of the deployment process, and a second mode of rapid and easy deployment.

Moreover, additional advantages may include: (i) an integrated and ergonomic handle for easily and effectively operating the stent delivery system of the present invention; (ii) a locking mechanism capable of resisting inadvertent or accidental movement or retraction of the stent delivery system components during packaging, sterilization, shipping, storage, handling and preparation; and (iii) a capability of holding the delivery system components in a fixed relative position during an intermediate point in deploying a medical device.

The particular embodiment of the present invention selected for illustration in the drawings includes a handle 10, shown in detail in Figures 1-10. An upper and lower main body housing 12 and 14 are arranged in a top-and-bottom configuration, as shown for example in Figures 1 and 3. Other components include inner and outer shaft members

16 and 18 respectively, an anchoring member 20, a proximal hub 22 with an actuator or knob 24 and a corresponding flush lumen tube 26, as well as a threaded base member 30 and a rotating finger ring 32.

In addition, the handle of the present invention preferably has a locking mechanism 28 for releasably locking the outer shaft member 18 in an initial position relative to the handle 10 and the inner shaft member 16, by resisting movement of the rotating finger ring 32 relative to the upper and lower body housings 12 and 14, and thus preventing motion of the threaded base 30 and proximal hub 22.

The lower main body housing 14 preferably has several gripping knurls 34 for providing a physician with a good gripping surface, while the upper main body housing 12 has a longitudinal slot 36 defining a channel for sliding the movable actuator 24 and thus limiting the extent of possible travel for the actuator 24 and proximal hub assembly 22. Together, the upper and lower body housings 12 and 14 define openings 38 through which a physician can operate the rotating finger ring 32, a proximal anchoring aperture 40 adapted to capture a portion of the anchoring member 20, a distal shaft aperture 42 through which the inner and outer shaft members 16 and 18 extend, and several internal openings for receiving fasteners 44 to hold the main body housings 12 and 14 together. They also define a circular annular bearing shelf or shoulder 46.

In the preferred initial configuration, proximal hub 22 is affixed to threaded base 30, which rotatably carries rotating finger ring 32. A distal surface of rotating finger ring 32 touches and bears on shoulder 46 of main body housing 12. Rotation of the rotating finger ring 32 causes it to press on shoulder 46 and pull on threaded base 30, resulting in very precise and sensitive withdrawing movement of outer shaft member 18 in a

proximal direction. Then, when more rapid proximal withdrawal of the outer shaft member 18 is desired, the physician may grasp the actuator 24 and swiftly draw the hub 22 directly back in the proximal direction.

In the particular assembly shown in the drawings, main body housings 12 and 14 are held together by fasteners 44. Anchor aperture 40 fixedly receives anchor 20, which is affixed to the proximal end of inner shaft member 16. A proximal end of outer shaft member 18 is affixed to proximal hub 22, with a flexible strain relief 48 protecting the joint.

An example of operating the medical device delivery system of the present invention is graphically depicted in Figures 11-14, which include illustrations of a handle 54 having a different appearance than handle 10 shown in Figures 1-10. In operation, the distal end 56 of the medical device delivery system is preferably directed into a patient via a body passageway. The medical device delivery system may preferably follow along a guidewire (not shown), and/or travel through a previously placed guiding catheter (not shown), until the distal end 56 is at a desired location for treatment. As shown in Figure 11, the distal tip 56 has preferably crossed the site of a lesion or stenosis 58. When the device is properly in an initial position, the physician releases or breaks off the lock of the present invention. A single embodiment of the lock is illustrated in Figures 1 and 4, and of course the present invention encompasses a multitude of various lock configurations, including pins, clamps, breakable members, spring-loaded locks, splines, or keys. The lock may be releasable only once, or may be capable of repeatedly being engaged and released. For example, the lock shown in Figures 1-10 may be initially

released by squeezing the components, and then used to re-lock the system in another position or configuration, such as for example that shown in Figure 13.

Such a locking mechanism preferably resists inadvertent or accidental movement or retraction of the stent delivery system components during packaging, sterilization, shipping, storage, handling and preparation.

After the lock is released, the preferred operation of the present invention may be accomplished by first rotating the finger ring 60 to cause it to advance on threaded base 62 and press against shoulder 64, such that the entire assembly of threaded base 62, proximal hub and outer shaft member 66 withdraw proximally with respect to handle 54, and thus with respect to inner shaft member 68. This first method of withdrawing the outer sheath 66 allows precise and sensitive adjustment.

As shown in Figures 11 and 12, the physician may rotate the finger ring 60 slightly, to pull the outer sheath 66 back slightly. This small movement exposes a small portion of the medical device, in this case a stent 50, as shown in Figure 12. In this configuration, the handle of the present invention will hold the outer sheath 66 in position relative to the inner body 68, resisting further inadvertent expansion of the stent 50. The physician then has the time and flexibility of procedure to selectively optimize and make any final adjustments to the position of the medical device and delivery system within the desired site, as illustrated by the arrow in Figure 12. This precise adjustment of the position of the stent 50, before any portion of the stent 50 touches the body passage or vessel 70 in a manner that might inhibit further positional adjustment, is preferable.

When the physician is satisfied with the positioning, as it appears on a fluoroscopic x-ray video screen, the physician may continue to rotate the finger ring 60 to further withdraw the outer sheath 66, as shown in Figure 13.

Upon initial contact of the stent 50 with the vessel wall, or when the stent is expanded sufficiently to independently hold its position, or at any desired point, the physician may simply grasp knob 72 and pull or push it along slot 74, as depicted by the arrow in Figure 14. This second method of withdrawing the outer sheath 66 allows relatively large-scale and rapid movement, at whatever speed the physician wishes, to quickly deploy the medical device.

Various materials may be selected for the components of the present invention, including any material having the desirable performance characteristics. In the particular embodiment shown in the drawings, the inner and outer shaft members 16 and 18, strain relief 48, and distal tip 56 may be made of any biocompatible and suitably flexible yet sufficiently strong material, including polymers of various types. Possible selections for such materials include nylons or polyamides, polyimides, polyethylenes, polyurethanes, polyethers, polyesters, etc. In the alternative, some portion or all of the inner and/or outer shaft member 16, 18 may be formed of a flexible metal, including for example stainless steel or nitinol hypotube. The stent 50 is preferably made of any biocompatible material that is strong and rigid, including for example stainless steel, platinum, tungsten, etc. The components of the handle of the present invention are preferably made of a material that is strong and rigid, including for example inflexible polycarbonates, or even some metal components.

Of course, many different variations are included within the scope of the present invention. Some of these variations or alternative embodiments include any possible arrangement of sizes, materials, and designs within the bounds of the following claims.

In addition, the inner shaft member 16 assembly, including anchor 20, inner shaft member 16 and distal tip 56, may preferably be provided with a through lumen adapted to receive a guidewire.

It should be understood that an unlimited number of configurations for the present invention could be realized. The foregoing discussion describes merely exemplary embodiments illustrating the principles of the present invention, the scope of which is recited in the following claims. Those skilled in the art will readily recognize from the description, claims, and drawings that numerous changes and modifications can be made without departing from the spirit and scope of the invention.